AN INTEGRATED APPROACH FOR THE MANAGEMENT OF HYPERTENSION WITH DYSLIPIDEMIA THROUGH AYUSH SYSTEM OF MEDICINE: A CASE STUDY

| Tushita Thakur | Consultant Homoeopathic Physician, AYUSH Wellness Clinic, President's Estate, New Delhi-110004 | | | | |
|--|---|--|--|--|--|
| Izharul Hasan | Consultant Unani Physician, AYUSH Wellness Clinic, President's Estate, New Delhi- 110004 | | | | |
| Arun Kumar Bhadula | Consultant Ayurvedic Physician, AYUSH Wellness Clinic, President's Estate, New Delhi-110004 | | | | |
| Vinod Kumar Shahi | A.D. (Ay), CCRAS & Co-ordinating Officer, AYUSH Wellness Clinic, President's Estate, New Delhi-110004 | | | | |
| ABSTRACT) Hypertension with dyslipidemia is a major health problem globally. It is also a major risk factor for cardiovascular | | | | | |

diseases like coronary heart disease and stroke that have high worldwide mortality. India has a high public health burden of hypertension with dyslipidemia, the condition being directly responsible for nearly 57% of all stroke deaths and 24% of all Coronary Heart Disease (CHD) deaths. There are large number of patients on conventional treatment who continue to have uncontrolled blood pressure and look for alternative systems of medicines. In this scenario, Ayurveda, Unani and Homoeopathy system of medicine have potential to help in reducing the proportion of the hypertension with dyslipidemia among suffering population and thereby make a contribution in reducing overall cardiovascular mortality levels. The holistic nature Ayurveda, Unani and Homoeopathy system of medicine makes it a more attractive option at the community level.

This study reports statistically significant improvement in levels of diastolic BP (p=0.042), triglycerides (p=0.028) and HDL (p=0.035) by using combination of Ayurvedic Swedana therapy, Unani Wet cupping therapy (WCT) and Homoeopathic preparation of Rauvolfia serpentina mother tincture as per study protocol. These results highlight that intergrated approach to Hypertension with dyslipidemia using Ayurveda, Unani and Homoeopathy system of medicine has promising results and warrant further studies with more stringent criteria.

KEYWORDS : AYUSH, Cupping therapy, Rauvolfia serpentina, Swedana

INTRODUCTION

Hypertension, or high blood pressure, is the constant pumping of blood through blood vessels with excessive force. It is one of the most important causes of premature death worldwide with mortality rate of 8 million people every year¹. India has a high public health burden of hypertension with dyslipidemia, the condition being directly responsible for nearly 57% of all stroke deaths and 24% of all coronary heart disease (CHD) deaths^{2,3}.

High blood pressure is called the "silent killer" because it often has no warning signs or symptoms. However it may present with earlymorning headache, nosebleed, irregular heartbeats and buzzing in the ears. Symptoms of severe hypertension may include tiredness, nausea, vomiting, confusion, anxiety, chest pain and muscle tremors. Hypertension can be hereditary and the risk for high blood pressure can increase even more when heredity is combined with unhealthy lifestyle choices. Behaviour and lifestyle-related factors that increase hypertension risk include eating too much salt (sodium), not eating enough potassium (from fruits and vegetables), being overweight, not getting enough exercise, as well as drinking too much alcohol and smoking. Nearly 60% of diabetics also have high blood pressure⁴.

The WHO-ISH classification of blood pressure is given below5:

| Category | Systolic BP (mm of Hg) | Diastolic BP(mm of Hg) |
|-------------------------------------|---------------------------|---------------------------|
| Optimal | <120 | <80 |
| Normal | <130 | <85 |
| High normal | 130-139 | 85-89 |
| Hypertension Grade I (Mild) | 140-159 | 90-99 |
| Hypertension Grade II (Moderate) | 160-179 | 100-109 |
| Hypertension Grade III (Severe) | >180 | >110 |
| Isolated Systolic Hypertension | >140 | <90 |

Dyslipidemia is derangements of one or more of the lipoproteins in blood, such as total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), and/or triglycerides (TG), or low levels of high-

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density lipoprotein cholesterol (HDL-C) alone⁶. LDL-C levels are positively correlated with CVD risk, whereas HDL-C levels are inversely correlated⁷. High total serum cholesterol levels and high LDL-C are well established risk factors for Coronary artery disease⁸.

Conventionally, angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), beta-blockers, calcium channel blockers (CCBs) and diuretics are prescribed singly or in combination for the treatment of hypertension⁹. Statin is the first-line of treatment for dyslipidemia¹⁰. However, there are large number of patients on conventional treatment who continue to have uncontrolled blood pressure and look for alternative systems of medicines. This study reports the efficacy of integrated Ayurvedic, Unani and Homoeopathic treatment for Hypertension with dyslipidemia.

MATERIALSAND METHODS

Already diagnosed cases of uncontrolled hypertension (systolic < 200 mmHg and Diastolic < 120 mmHg) with dyslipidemia on conventional treatment for at least 1 year duration, attending the OPD of AYUSH Wellness Clinic, President's Estate, willing to be a part of this study were enrolled as per inclusion and exclusion criteria. They also underwent laboratory investigations, which included a blood count, urine for protein, glucose and blood, blood urea and Serum creatinine, serum cholesterol, random blood glucose to exclude any other possible abnormality

Inclusion criteria

- History, examination and routine investigations show no evidence of secondary causes of hypertension.
- 2. Age group patients within 35 65 years of age
- 3. Sex Both sexes included
- 4. Patient willing to participate and provide written consent

Exclusion criteria

- Cases falling into the very high risk group (systolic > 200 mmHg and Diastolic >120 mmHg)
- 2. Cases with wide fluctuations of blood pressure
- 3. Cases with serious illnesses or conditions affecting the function of different organs or systems e.g. hepatic disorders, impaired renal

function, CAD and Diabetes.

- Pregnant and lactating mothers
- 5. Any other condition that may jeopardise the study

Treatment protocol

The feasibility of a placebo-controlled study was examined, but was rejected because of ethical and logistical reasons. The enrolled cases were prescribed Homoeopathic medicine Rauvolfia mother tincture 10 drops twice a day orally in half cup drinking water half an hour before breakfast and dinner every day. Along with this, *Unani* procedure Alhijama (Wet cupping therapy) and *Ayurvedic sudation* (*Sarvanga Swedana*) was done. Wet cupping therapy (WCT) was performed once in a week for two consecutive months whereas *Sarvanga Swedana* was given on next day of WCT for 7 consecutive days on alternate weeks for period of two months. The patients were asked to continue with their conventional medicine during the study period. The total duration of intervention including follow up was two months. The WCT was done by Unani Consultant and *Swedana thereapy* was administered under the strict supervision of *Ayurveda* Consultant.

Procedure for Wet Cupping Therapy (WCT) or Al-hijama:

WCT or Al-hijama has six steps including demarcation, sterilization, dry cupping of the desired site, puncturing, cupping and sterilization. The hijama was carried out on four sites of the body. The first site is between the two scapulas, opposite the T1-T3 scapular spine (Al-Kahil), as done in Zarei's study". The second site is located on the seventh cervical vertebra (GV14), as done in *Guo*'s study¹². The other 2 sites are on both sides of the neck. They are located 2 fingers posterior to the angle of the mandible on both sides, just below the skull bone, on the hair line (Al-Akhdaain). The procedure adopted for this study is described as follows: Clean the areas with alcohol swab and put the cup on the area to start suction process. Gently take off the cup and make few very superficial incisions (with help of surgical blade no.11) parallel to each other. Replace the cup on the same area and repeat suctioning. Remove the cups, clean the area and do dressing. In the present study, four hijama sessions were conducted per month for two consecutive months. The duration of single session of WCT was 10-15 minutes

Procedure for Swedana Therapy:

Patients receiving cupping therapy were asked to come for Swedana on next day of cupping therapy. Swedana therapy was given for total duration of 28 days (7 days a week for 4 weeks alternatively) excluding the day of cupping therapy. Every selected patient was explained about the procedure.. Thorough clinical examination of the patients was conducted each day before therapy. Blood pressure was measured before and after therapy with the help of mercurial sphygmo manometer. Patients were advised to drink a glass of water before therapy to avoid any dehydration. Patients recommended for Sarvanga Swedana were initially given snehana (whole body oil massage) with Tila taila. After snehana, the patients were asked to lie supine in the Sarvanga Swedana chamber (lying type) and head of the patient was kept outside the chamber. Herbal decoction steam of Dashmoola - An Avurvedic medicine (prepared after mixing the coarse powder of Dashmoola with 8 times water then boiled and reduced to one - fourth) was used for Swedana of patient. The patient was given Swedana in lie down supine position for 5-10 minutes. Then the lid of the chamber was opened allowing the patient to come out slowly and sit on a chair for approximately 1-2 minutes. During the whole procedure, the head of the patients was covered with a small wet towel. The patients were then allowed to change in the room (without a direct air exposure) before leaving.

Therapeutic lifestyle changes advised to the patients:

The following therapeutic lifestyle changes were advised to the patients:

- 1. Weight reduction
- 2. Restriction of sodium intake
- 3. Reduction in dietary fat and cholesterol
- 4. Avoidance of tobacco
- 5. Restriction of alcohol consumption
- 6. Regular physical exercise

Assessment parameters adopted

The outcome measure is blood pressure values and lipid profile values after the period of the study. These were compared with the initial values, and the difference analyzed using statistical tests, to find the efficacy or otherwise of the treatment.

Statistical analysis

The data was analysed using descriptive analysis in the form of mean, standard deviation, standard error and median. Paired-t test was applied to determine the difference between subjects before and after treatment. The level of significance was set at 5%. All analysis was performed using GraphPad prism 7.

RESULTS

The results of this study are presented in form of graphs and tables below:

Fig. 1: BP measurement Before & After treatment

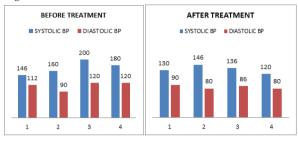


Table 1: Systolic BP results before and after treatment

| BP | Systolic BP (N=4) | | | Diastolic BP (N=4) | | | |
|----------------|-------------------|--------|------------|--------------------|--------|---------|--|
| measurements | BT | AT | Difference | BT | AT | Differe | |
| | | | | | | nce | |
| Mean | 171.50 | 133.00 | 38.50 | 110.50 | 84.00 | 26.500 | |
| Standard | 23.573 | 10.893 | 27.197 | 14.177 | 4.899 | 13.304 | |
| deviation (SD) | | | | | | | |
| Standard error | 11.786 | 5.447 | 13.598 | 7.089 | 2.449 | 6.652 | |
| Minimum | 146.00 | 120.00 | 14.000 | 90.00 | 80.00 | 10.000 | |
| Maximum | 200.00 | 146.00 | 64.000 | 120.00 | 90.00 | 40.000 | |
| Median | 170.00 | 133.00 | 38.000 | 116.00 | 83.00 | 28.000 | |
| Lower 95% CI | 134.00 | 115.67 | -4.770 | 87.944 | 76.206 | 5.333 | |
| Upper 95% CI | 209.00 | 150.33 | 81.770 | 133.06 | 91.794 | 47.667 | |

The two-tailed P value for systolic BP is 0.0661 which is not significant, t= 2.831 with 3 degrees of freedom. The co-relation coefficient (r) is -0.1272, the Kolmogorov-Smirnov distance (KS) is 0.30, P value>0.10 and the data passed normality test with P>0.05.

The two-tailed P value for diastolic BP is 0.0283 which is significant, t=0.4612 with 3 degrees of freedom. The co-relation coefficient (r) is -0.3455, the Kolmogorov-Smirnov distance (KS) is 0.21, P value>0.10 and the data passed normality test with P>0.05.

Table 2: Total cholesterol results before and after treatment

| | Total | | | Triglycerides | | | HDL (N=4) | | |
|-----------|------------------|-------|-------|---------------|-------|--------|-----------|-------|--------|
| | cholesterol(N=4) | | | (N=4) | | | | | |
| | BT | AT | Diffe | BT | AT | Differ | BT | AT | Differ |
| | | | renc | | | ence | | | ence |
| | | | e | | | | | | |
| Mean | 173.50 | 166.0 | 7.50 | 269. | 133.7 | 135.7 | 26.500 | 30.25 | -3.750 |
| | | 0 | 0 | 50 | 5 | 5 | | 0 | |
| Standard | 46.321 | 25.29 | 32.5 | 62.7 | 33.27 | 68.29 | 3.109 | 4.646 | 2.062 |
| deviation | | 8 | 22 | 67 | 0 | 5 | | | |
| (SD) | | | | | | | | | |
| Standard | 23.161 | 12.64 | 16.2 | 31.3 | 16.63 | 34.14 | 1.555 | 2.323 | 1.031 |
| error | | 9 | 61 | 83 | 5 | 8 | | | |
| Minimum | 139.00 | 142.0 | -35.0 | 206. | 94.00 | 70.00 | 22.000 | 24.00 | -6.000 |
| | | 0 | 00 | 00 | 0 | 0 | | 0 | |
| Maximu | 140.00 | 198.0 | 42.0 | 352. | 170.0 | 231.0 | 29.000 | 35.00 | -2.000 |
| m | | 0 | 00 | 00 | 0 | 0 | | 0 | |
| Median | 157.50 | 162.0 | 11.50 | 260. | 135.5 | 121.0 | 27.500 | 31.00 | -3.500 |
| | | 0 | 0 | 00 | 0 | 0 | | 0 | |
| Lower | 99.803 | 125.7 | -44.2 | 169. | 80.81 | 27.09 | 21.553 | 22.85 | -7.030 |
| 95% CI | | 5 | 42 | 64 | 7 | 2 | | 9 | |
| Upper | 247.20 | 206.2 | 59.2 | 369. | 186.6 | 244.4 | 31.447 | 37.64 | -0.470 |
| 95% CI | | 5 | 42 | 36 | 8 | 1 | | 1 | 1 |

The two-tailed P value for Total Cholesterol is 0.6760 which is not significant, t= 3.984 with 3 degrees of freedom. The co-relation

coefficient (r) is 0.7373, the Kolmogorov-Smirnov distance (KS) is 0.19, P value>0.10 and the data passed normality test with P>0.05.

The two-tailed P value for Triglycerides is 0.0285 which is significant, t=3.975 with 3 degrees of freedom. The co-relation coefficient (r) is 0.09154, the Kolmogorov-Smirnov distance (KS) is 0.28, P value>0.10 and the data passed normality test with P>0.05.

The two-tailed P value for HDL is 0.0358 which is significant, t= 3.638 with 3 degrees of freedom. The co-relation coefficient (r) is 0.9346, the Kolmogorov-Smirnov distance (KS) is 0.30, P value>0.10 and the data passed normality test with P>0.05.

Table 3: Summary of final results

| | BT (Mean ± SD) | AT (Mean ± SD) | Result of Paired t test | |
|------------------------------------|--------------------|---|----------------------------|---------|
| | | | T value | P value |
| Mean of Systolic BP (mm of Hg) | 171.50 ± 23.57 | $\begin{array}{r}133.00\pm\\10.89\end{array}$ | 2.831 | 0.066 |
| Mean of Diastolic BP (mm of Hg) | 110.50 ± 14.17 | 81.50 ± 17.08 | 3.394 | 0.042 |
| Mean Cholesterol (mmol/L) | 173.50 + 46.32 | 166.00 + 25.29 | 0.461 | 0.676 |
| Mean Triglyceride (mmol/L) | 269.50 + 62.76 | 133.75 + 33.27 | 3.975 | 0.028 |
| Mean HDL (mmol/L) | 26.50 + 3.10 | 30.25 + 4.64 | 3.638 | 0.035 |

DISCUSSION

Cupping therapy was used in Egypt dating back some 3,500 years. The earliest recorded use of Cupping is from the famous Taoist alchemist and herbalist, Ge Hong (281-341 A.D.). In ancient Greece, Hippocrates recommended the use of cups for a variety of ailments, while in the early 1900's eminent British physician, Sir Arthur Keith, wrote how he witnessed Cupping performed with excellent success. In China, extensive research has been carried out on Cupping, and the practice is a mainstay of government-sponsored hospitals of Traditional Chinese medicine^{13,14}. According to the Taiba Theory in the Unani System of medicine, the negative pressure applied by cups during WCT causes increased capillaries infiltration. It results in local collection of filtered fluids, lymph and interstitial fluid in that area and dilutes chemical substances, inflammatory mediators, and nociceptive substances, bathes nerve endings in collected fluids and breaks tissue adhesions. Following the puncturing of that area and by applying negative pressure once again, the fluids are evacuated and prevented from being reabsorbed by venous capillaries. This drawing out of impurities from the deeper tissues may help to regain homeostasis in the human body¹⁵.

Large scale systematic reviews (Cao et al, 2010, 2012) that reviewed 73 RCTs and 135 RCTs respectively have consistently reported no serious side effects of WCT^{16,17}. Zarei et al, 2012 published a RCT on the effect of wet cupping on blood pressure in 35-60 year old patients diagnosed with hypertension among 42 patients. The comparison of the means of systolic and diastolic blood pressures and independent-t test at the beginning of the study and end of the 6 week study within the cupping group showed significant difference in the Systolic blood pressure but not in the diastolic blood pressure¹¹. Izhar et al (2014) have published a case report on efficacy of wet cupping on hypertension¹⁸. Aleyeidi et al, 2015 have reported a RCT on the effect of wet cupping on blood pressure among 18 participants aged between 19-65 years. The cups were applied on the same sites as in previous studies; however the results of this study showed no significant difference in the SPP or DBP between the hijama and control groups after 4 weeks of follow up¹⁹.

Swedana according to the Ayurvedic concept, causes the body's channels to widen, enabling Ama or toxins to easily flow from the tissues back to the GI tract and improve circulation. Heat allows the skin and blood (outer disease pathway) to be cleansed. This relieves, cleanses, and reduces fat tissue and muscle tension. Heat also restores balance to Vayu and Kapha (i.e., removing coldness and stiffness) and reduces the heavy, sticky nature of Ama. Published literature has reported that rise in temperature during Swedana is positively related to increased tissue metabolism and removal of waste products through lymphatic system²⁰. Further, passive heating during Swedana

substantially increases the cutaneous vascular conductance followed by a corresponding increase in systemic conductance. A barometric homeostasis; however, is maintained in such cases by corresponding decrease of conductance at non-cutaneous beds and also by corresponding increase of the cardiac output. A reduction in central venous pressure (CVP) occurs almost immediately with the onset of passive heating. This reduction is presumed to be the cause of increased cardiac output and also a redistribution of blood from central to peripheral circulation. In a non-randomized time control study to evaluate effects of passive body heating on parameters such as alteration of central blood volume and systemic blood volume distribution noted an increased cutaneous conductance and heart rate²¹.

A study was conducted to assess the changes in physiological and biochemical parameters due to Steam bath and it was observed that in majority of the cases, there was a decrease in serum sodium and chloride level with corresponding increase in potassium level. As sodium and chloride are major cation and anion of extra cellular fluid respectively, when there is heat stress or any conditions leading to fluid loss is associated with their loss. To compensate this loss of sodium and chloride; potassium which is major cation of intracellular fluid, moves in to extra cellular fluid to maintain homeostasis. This may be the reason for decrease of sodium and chloride with a corresponding increase in potassium levels, however, the changed values are within the normal range. Heart rate increases by 10 beats per minute for 1° F rise in temperature. Increase in blood temperature and reflex stimulation of adrenergic cardiac beta-receptors is the likely mechanism of heart rate increase and increased metabolic rate also increases heart rate. But when the temperature is returned to normal level after half an hour, the pulse rate reaches to baseline level as before Swedana. Effect of Bashpa Swedana on Blood pressure-It is observed in the study that B.P has fallen immediately after Swedana with a mean of 7.94 in systolic blood pressure and 9.75 in diastolic blood pressure and was normalized gradually after half an hour though there is a rise in heart rate which reached to base line level after half an hour. During Swedana, there is temperature rise and so heart rate increases. This should cause a rise in cardiac output and stroke volume leading to increase in blood pressure. But heat reduces viscosity of blood. So BP decreases. Viscosity decreases about 2% for each 1°C rise in temperature. Reduced blood viscosity in turn reduces the peripheral resistance, which is also reducing by vasodilatation, leading to a fall in blood pressure²²

Rauvolfia serpentina is a perennial shrub from the Apocynaceae family. It is native to the moist, deciduous forests of Southeast Asia, including India, Burma, Bangladesh, Sri Lanka, and Malaysia. The plant was mentioned in Indian manuscripts as long ago as 1000 BC and is also known as sarpagandha and chandrika²³. Rauvolfia contains many different phytochemicals, including alcohols, sugars and glycosides, fatty acids, flavonoids, phytosterols, oleoresins, steroids, tannins, and alkaloids. The most important alkaloids found in the plant are indole alkaloids that are found in highest concentration in the bark of the root. This medicine has been used in Indian folk medicine for thousands of years to treat snake and insect bites, febrile conditions, malaria, abdominal pain, and dysentery²⁴. Over 50 different indole and indoline alkaloids have been isolated in this plant. The most pharmacologically active indole alkaloids are ajmaline, deserpidine, rescinnamine, reserpine, serpentine, and yohimbine. The BP lowering effect is due to resperine alkaloid present in Rauvolfia²⁵.

In 1940, Vakil made the 1st recorded reference to the therapeutic application of Rauwolfia in cases of human hypertension²⁶. Further studies that corroborated the efficacy and safety of Rauwolfia in hypertension include Chakravarty *et al* $(1951)^{27}$, Vida $(1952)^{28}$, Arnold and Bock $(1953)^{29}$, Sarre $(1953)^{30}$ and Klausgraber $(1953)^{31}$ among others. Vakil (1955) showed that Rauwolfia was a useful antihypertensive remedy, capable of lowering both systolic and diastolic pressures, free of serious ill effects, easy to administer, and applicable to most cases of high blood pressure in a series of 100 cases of essential hypertension³².

The homoeopathic proving of this medicine was made by Dr. W. Templeton published in British Homoeopathic Journal in the year 1955³³. Standard homoeopathic repertories including Synthesis repertory and Murphy's repertory have described Rauvolfia serpentina as a medicine for hypertension^{34,35}. Published studies have reported the efficacy of homoeopathic preparation of Rauvolfia in hypertension and dyslipidemia^{36, 37}. Rastogi et al (1996) in their study prescribed

Rauwolfia serpentina in 1x potency (2 pinch in half a cup of water orally given 3 times a day) to 52 patients suffering from essential hypertension. Later, after clinical improvement in blood pressure (BP), its repetition was reduced to twice and then to once daily. BP has been reduced in 42 patients subsequent to treatment. Further, 22 patients of 52 who were under allopathic treatment were tapered off their later treatment and slowly withdrawn. Associated symptoms and pathological findings were also relieved and improved³⁶. A prospective observational study on hyperlipoproteinemia carried out during the period April 1992-March 2003 in which 322 patients were studied. Inclusion criteria was patients above the age of 30 years, with cholesterol > 200mg/dl, triglycerides >170mg/dl, LDL > 150mg/dl, VLDL > 50mg/dl and HDL < 35 mg/dl. Specific parameters were followed to assess the intensity of complaints and the improvement status. Homoeopathic medicines were prescribed in different potencies (Q to 10M), basing on the presenting complaints, mental and physical attributes of the patients. The patients were advised to have low calorie diet and regular exercise. Parameters used are when patient is asymptomatic and lipid profile touched normal level, and there is no recurrence for 3 years. Of the 322 patients enrolled for the study 293 were followed up regularly and varying degrees of improvement were observed, viz. marked improvement in 77 patients, moderate improvement in 113 patients, mild improvement in 100 patients and no improvement in 03 patients. Results obtained were encouraging and confirmed the usefulness of Homoeopathic medicines, i.e., Lycopodium, Rhus tox, Sulphur, Calcarea carbonica, Lachesis, Pulsatilla, Bryonia alba, Nux vomica., Abroma augustum, Gelsemium and Rauvolfia serpentina. Rauvolfia mother tincture was prescribed 10 drops thrice a day to 10 patients of whom 7 improved 37. The safety profile of Rauwolfia serpentina mother tincture (containing 77% v/v alcohol) has been investigated in the Department of Pharmacology at AIIMS, New Delhi. Acute and sub-acute oral toxicity was studied in adult male Wistar albino rats after oral administration as per OECD (Organisation for Economic Co-operation and Development) - 423 guidelines and OECD guidelines for testing of chemicals - 407. The results of this study indicated that there were no acute toxic symptoms observed in tested animals. Results of sub-acute toxicity study did not show any change in body weight, haematological and biochemical parameters as compared to control. The histopathological examination of kidney and liver also did not reveal any organ toxicities³⁸

The results of present study are statistically significant improvement in levels of diastolic BP (p=0.042), triglycerides (p=0.028) and HDL (p=0.035).

SCOPE AND LIMITATIONS OF THE STUDY

While the results of this study are promising, this is essentially a preliminary study due to small sample size. Clinical study with larger sample size and longer follow up duration may be undertaken to further validate the results of this study.

CONCLUSION

Hypertension with dyslipidemia is a major health problem globally. It is also a major risk factor for cardiovascular diseases like coronary heart disease and stroke that have high worldwide mortality. Conventional anti-hypertensive treatment, while effective in reducing the blood pressure, has its own draw backs including adverse effects of drugs and high cost of treatment. In this scenario, as highlighted by the results of this study the integrated approach to Hypertension with dyslipidemia using Ayurveda, Unani and Homoeopathy system of medicine has promising results and warrant further studies with more stringent criteria.

ACKNOWLEDGEMENT

We gratefully acknowledge Mrs. Anjali BM Bakshi, Joint Director, Rashtrapati Bhavan for her constant encouragement and support to carry out this work. We offer our sincere thanks to Dr. V K Shahi, A.D. (Ay), CCRAS, Ministry of AYUSH & Co-ordinating officer, AWC, Rashtrapati Bhavan for his guidance. We also thank Abdul Kalam, Ayurveda therapist, Ammar Farooqi, Unani therapist and Tarun Kumar, Homoeopathic pharmacist for their contribution in this work.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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